K010473

JUN - 6 2001

II. Summary and Certification

A. 510(k) Summary of Safety and Effectiveness

1. Submitter's Name

a. Address

ATC Technologies, Inc.
80 Cummings Park
Woburn, Massachusetts 01801

b. Phone Number

(781) 939-0725

c. Contact Person

Paul C. Kierce, President

d. Summary Preparation Date

February 9, 2001

2. Device Name

a. Trade/Proprietary Name

The trade name selected for the Candidate Devices is SparrowHawk™.

b. Common/Usual Name

Endomyocardial Biopsy Forceps, Biopsy Forceps, or Bioptomes

c. Classification Name

Endomyocardial Biopsy Forceps

3. Predicate Devices

The Candidate Devices are substantially equivalent to the following legally-marketed devices ("Predicate Devices"):

Device Name: Jawz EMB Forcep (Contract manufactured for Argon by Portlyn)
Manufacturer: Argon Division of Maxxim Medical
510(k) Number: K951447
Substantial Equivalence Date: 07/27/95

Device Name: Portlyn DynaBite Cardiovascular Biopsy Forceps
Manufacturer: Portlyn Corporation
510(k) Number: K951447
Substantial Equivalence Date: 07/27/95

4. Device Description

a. Function

The Candidate Devices consist of sterilized, disposable Endomyocardial Biopsy Forceps. They are used in catheterization procedures to remove histological tissue samples from the inner walls of the heart.

b. Scientific Basis

The Candidate Devices are radiopaque and consist of stainless steel cutting jaws, a wire coil outer jacket, and a 3-ring handle. The Candidate Devices are available both with and without an optional fluorinated ethylene-propylene ("FEP") coating, which improves lubricity during insertion in a commercially-available sheath introducer.

The thumb ring portion of the 3-ring handle is flexible and rotates to accommodate any thumb position. The stainless steel cutting jaws are closed on the specimen by moving the thumb ring toward the double rings. Closing of the jaws around the sample is facilitated by a spring in the handle. The jaws are opened by moving the thumb ring away from the double rings.

Candidate Device configurations which are 50 centimeters in length are intended for right ventricular biopsies using the jugular approach. Candidate Devices which are 105 centimeters in length are intended for right or left ventricular biopsies using the femoral approach.

c. Significant Physical/Performance Characteristics

1) Design

The Candidate Devices are manually-operated, hand-held, surgical instruments of either 1.5, 1.8, or 2.2 millimeter diameters. They are either 50 or 105 centimeters in working length and have a pair of double actuating, fenestrated or non-fenestrated cup jaws at the distal end. They will be available in either straight or pre-curved formats, and actuated by single or multi-stranded actuating wires. The coiled outer jacket may be uncoated or coated with FEP.

2) Materials

Both the Predicate and Candidate Devices are being manufactured from identical materials obtained from the same vendors.

3) Physical Properties

Diameter - 1.5, 1.8 or 2.2 millimeters.

Length - 50 or 105 centimeters.

The Candidate Devices are available with an optional FEP jacket coating. The FEP jacket coating improves lubricity during insertion in a commercially-available sheath introducer.

5. Intended Use Statement

a. Disease/Conditions

The tissue samples derived through use of the Candidate Devices are used to evaluate the histology of the heart in cases of cardiac transplantation and to screen patients with myocardiopathies or myocarditis.

b. Patient Population

According to the clinical judgment of the physician, the Candidate Devices are suitable for use on patients for which cardiac transplantation is considered and for screening patients with myocardiopathies or myocarditis.

6. Technological Characteristics Summary

Endomyocardial Biopsy Forceps are hand held, manually-operated devices. They are used in catheterization procedures to remove histological tissue samples from the inner wall of the heart.

B. Certification

The Predicate Devices are not Class III devices. Therefore, no Certification is required as part of this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

ATC Technologies, Inc.
c/o Mr. Paul Kierce
President
80 Cummings Park
Woburn, MA 01801

Re: K010473/S1
Trade Name: SparrowHawk™ Disposable Endomyocardial Biopsy Forceps
Regulation Number: 870.4075
Regulatory Class: II (Two)
Product Code: DWZ
Dated: May 7, 2001
Received: May 15, 2001

Dear Mr. Kierce:

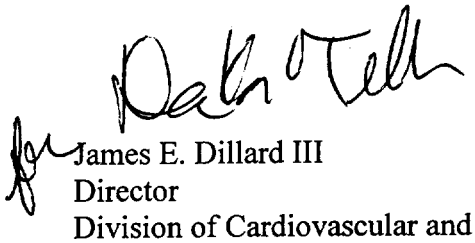
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

APPENDIX 11
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Not yet assigned~~. K010473

Device Name: SparrowHawk™ Disposable Endomyocardial Biopsy Forceps

Indications for Use: The Candidate Devices are indicated for use in patients needing endomyocardial biopsies. The biopsy tissue samples of the myocardium are pathologically tested for a variety of conditions which include:

1) early rejection following cardiac transplantation,
2) cardiomyopathies and myocarditis, and
3) detection of antracycline cardiotoxicity.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use XX **OR** **Over-The-Counter Use ___**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010473